Pediatric Advisory Committee Meeting
March 25, 2008
Hilton Washington DC North/Gaithersburg, Grand Ballroom,
620 Perry Parkway, Gaithersburg, Maryland

8:00 am	Welcome and Introductory Remarks	Marsha Rappley, MD Chair Dean, College of Human Medicine Michigan State University Carlos Peña, PhD, MS Executive Secretary Office of Science and Health Coordination OC, FDA
8:10 am	Agenda Overview	Dianne Murphy, MD Director, Office of Pediatric Therapeutics OC, FDA
8:20 am	**Brevibloc (esmolol HCl)** Abbreviated Review of Adverse Events	Amy Taylor, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER,FDA
8:25 am	**Toprol XL (metoprolol)** Abbreviated Review of Adverse Events	Amy Taylor, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER,FDA
8:30 am	**Lotensin (benazepril)** Abbreviated Review of Adverse Events	Amy Taylor, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER,FDA
8:35 am	**Coreg (carvedilol)** Standard Review of Adverse Events	Felicia Collins, MD, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
9:00 am	*Clarification Questions and Questions to the Committee*	
9:30 am	**Eloxatin (oxaliplatin)** Standard Review of Adverse Events	Felicia Collins, MD, MPH, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
9:45 am	*Clarification Questions and Question to the Committee*	

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9:50 am	**Colazal (balsalazide)** Standard Review of Adverse Events	Felicia Collins, MD, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
10:10 am	*Clarification Questions and Question to the Committee*	
10:15 am	**Suprane (desflurane)** Standard Review of Adverse Events	Hari Cheryl Sachs, MD, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
10:30 am	*Clarification Questions and Question to the Committee*	
10:35 am	**Break**	
10:45 am	**Celebrex (celecoxib)** Overview of Safety From Clinical Trials for JRA	Jeffery Siegel, MD, Medical Officer OND/ODEII/Division of Anesthesia, Analgesia and Rheumatology Products (DAARP), CDER, FDA
11:00 am	**Celebrex (celecoxib)** Standard Review of Adverse Events	Hari Cheryl Sachs, MD, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
11:15 am	*Clarification Questions*	
11:30 am	**Pfizer Comments**	Gail Cawkwell, MD Medical Team Leader for Celebrex Pfizer

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11:45 am	*Clarification Questions and Question to the Committee*	
12:00 pm	Lunch	
1:00 pm	*Open Public Hearing*	
2:00 pm	**Introduction to Update**	Dianne Murphy, MD Director, Office of Pediatric Therapeutics OC, FDA
2:05 pm	**Updates on Previous PAC Request** Trileptal (oxcarbazepine)	Evelyn Mentari, MD, MS Medical Officer, Division of Neurology Products CDER
2:25 pm	**FDAAA 2007 – Pediatric Perspective Update**	**Brief Overview of Legislation** Dianne Murphy, MD Director, Office of Pediatric Therapeutics FDA **Implementation and the Pediatric Expert Review Committee and CDER Changes** Lisa Mathis, MD Office of New Drugs Associate Director Pediatric and Maternal Health Staff, CDER, FDA **Safety Update, Biologics and Devices** Judith Cope, MD, MPH Medical Officer Office of Pediatric Therapeutics FDA
4:25 pm	*Questions*	
5:00 pm	**Adjourn**	Dianne Murphy, MD Director, Office of Pediatric Therapeutics OC, FDA FDA